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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,226	11/01/2006	Alastair Edwin McAuley	1171/44578/166-PCT-US	7568

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105 West Adams Street
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EXAMINER

Blizzard, Christopher James

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3771

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/570,226	Applicant(s) MCAULEY ET AL.	
	Examiner CHRISTOPHER BLIZZARD	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-13,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-13,16 and 17 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02/26/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/31/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to preliminary amendment filed on 02/28/2006. As directed by the amendment; claims 3, 4, 6-11, and 13 were amended; 5, 14 and 15 were cancelled and claims 16 and 17 were added. Therefore, this application has claims 1-4, 6-13, 16 and 17 currently pending.

Claim Objections

1. Claim 1 is objected to because of the following informalities: The phrase "the boundary" should be "a boundary", as the boundary has not yet been defined. In addition, the applicant is reminded to keep claim terms consistent throughout, therefore the terms "patient interface" and "inference" should be amended to be consistent. Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 13, 16 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 13 recites the limit "...where said cushion extends below said user's chin", which claims non-statutory subject matter.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4 and 6-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Gunaratnam (7,066,178).

6. Regarding claims 1-4 and 6-12, Gunaratnam discloses a CPAP device for delivering a supply of gases to a user (column 1, lines 13-17) comprising a patient interface (figs. 1 and 6, multiple components including 42) in fluid communication with the supply of gas (column 3, lines 1-3), and an outlet member with cover (36) detachably connected (column 5, lines 39-41) to a slot (56) of the patient interface (figs. 4 and 5), wherein a boundary between the outlet member and patient interface forms a narrow outlet vent (32) that passes a portion of the expired gases of a user (fig. 6). The separation (32) between the interface (fig. 6, 42) and the cover (36) increases to a edge of the cover in order to diffuse said exhaled gas (column 3, lines 42-45), forming a long tapered slot between the top and bottom of the patient interface (42) (fig. 6). The patient interface could include any type of mask including a nasal mask or a full face mask (column 5, lines 15-19).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 13, 16 and 17 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gunaratnam (7,066,178).

9. Regarding claims 13, 16 and 17 Gunaratnam discloses a device for delivering a supply of gases to a user comprising a patient interface in the form of a full face mask (column 5, lines 18-19) in fluid communication with supply of gases including a rigid hollow body (15) and a flexible cushion (16). Gunaratnam did not disclose a definition for a full face mask comprising a mask that would cover the user's chin, though it would have been obvious to one of ordinary skill in the art at the time of the invention that a full face mask would have a cushion that would cover the user's chin while the device was in use in order to provide the advantage of a better seal.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jaffre (6,851,425) a patient interface with removable vent cover, Drew (6,581,594) a mask with removable vent cover, and Wandel (4,974,586) a mask with a tapering outlet vent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771